UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF WEST VIRGINIA

AstraZeneca AB and
AstraZeneca Pharmaceuticals, LP

Plaintiffs/Counter-Defendants,

vs. CIVIL ACTION NO.

1:18-cv-193

1:19-cv-203

Mylan Pharmaceuticals, Inc.,
and 3M Company, and
Kindeva Drug Delivery, L.P.,

Defendants/Counter-Claimants.

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Proceedings had in the telephonic status conference of the above-styled action on March 22, 2022, before Honorable Irene M. Keeley, District Judge.

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Tuesday Afternoon Session,

March 22, 2022, 1:00 p.m.

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THE COURT: Good afternoon. This is Judge Keeley, and I'm advised that we have counsel for the parties on the line, and so I'll begin by calling the case.

This is AstraZeneca AB, et al., versus Mylan, et al., 1:18-CV-193, which is the lead case, and 1:19-CV-203.

The purpose of today's call is to discuss the parties' status reports outlining their positions on the scope of the case on remand and to take up other matters that may arise.

Would counsel, beginning with AstraZeneca's counsel, please note your appearance.

MS. LAW: Yes. This is Sandra Law as local counsel for AstraZeneca. Also here is David Berl and Gary Rubman.

THE COURT: All right. Good afternoon to all of you. I just wanted to find out -- excuse me, Mr. Copland. Is Chris Carlton on the line for AstraZeneca? We were advised he would be.

MR. BERL: Yes, Your Honor, he is on the line.

THE COURT: Mr. Copland.

MR. COPLAND: Thank you, Your Honor. I am, of course, representing the defendants, as is William O'Brien, also counsel of record, and on the line are Shannon Bloodworth,

David Anstaett, Brandon White, Maria Stubbings, and Michael Laing of the Perkins Coie firm. Also attending but not appearing are in-house counsel for Mylan.

THE COURT: Mr. Copland, I know the court reporter will ask me to advise you that we could barely hear you, and if that's going to be the case with other counsel from Mylan, that's going to be an issue, so let me -- let me just hear, Ms. Bloodworth, can I hear your voice, please, to see if it's going to be satisfactory?

MS. BLOODWORTH: Yes, Your Honor. This is Shannon Bloodworth for Mylan and Kindeva.

THE COURT: That's fine. And who's going to be arguing, either in whole or in part, for Mylan, so I can determine if other voices are going to be strong enough on the call?

MS. BLOODWORTH: I think myself and Mr. Anstaett will be speaking, so Dave, over to you.

THE COURT: Together on the same phone?

MR. ANSTAETT: We are not on the same phone, Your Honor. This is David Anstaett on behalf of defendants.

THE COURT: Thank you. I can hear you.

And then for AstraZeneca, Mr. Berl, who will be arguing for AstraZeneca? And I just want to make sure that I can hear your voices and that the court reporter will be able to as well.

MR. BERL: Yes, Your Honor, this is David Berl, and I'll be arguing for AstraZeneca.

THE COURT: All right. So we can hear you, but it's a little muffled, not as clear as you might want it to be. I don't know if that's the consequence of a speakerphone, but --

MR. BERL: What about now, Your Honor? Is that better?

THE COURT: That's better.

MR. BERL: Great. Thank you.

THE COURT: And I won't want to interrupt, but if I think you are blurred or fading out, you know I'll have to do that because, as you know, we need the record.

MR. BERL: Of course.

THE COURT: And obviously you want me to hear it, too, and it may be a consequence of our federal Cisco phone in here. You know, it's our conference phone. It may be that you're fine and it's my phone, but whatever it is, we need to make sure. Thank you.

May I hear from each side as to how you think we ought to approach the issues this afternoon. So Mr. Berl, I'll start with you and then turn it over to Mylan's counsel after I hear what AstraZeneca's position on how we should approach this afternoon's issues is.

MR. BERL: Yes, Your Honor. Thank you very much. David Berl again from AstraZeneca.

As Your Honor knows, we filed on March 8th a motion for temporary restraining order and preliminary injunction to prevent Mylan from commercializing its products until trial in this case can occur. Yesterday Mylan filed an opposition to that motion for preliminary injunction addressing each of the issues that we had included in our motion.

As to one issue, that is, infringement of the '137 patent, Mylan indicated that it was providing a partial response, and in the event that its motion to strike Dr. Berkland's report were denied, it would seek to provide additional information, presumably an expert report. We're addressing that issue in additional briefing as well.

That's where we stand with respect to the preliminary injunction papers, and also there's the attendant motion to strike that Mylan filed and that we filed an opposition to that motion yesterday afternoon.

I think those are the two issues, and more generally I think the issue of the scheduling of further proceedings, including trial, is on the table, and how and whether to conduct preliminary injunction proceedings in advance of trial is likewise on the table per the parties' submissions to the Court.

THE COURT: All right. So I understand that's what's on the table. Your preference is to take up the motion to strike first?

MR. BERL: I think that would be a logical place to start.

THE COURT: Okay. Is Mylan in agreement with that?

MR. ANSTAETT: Yes, Your Honor. This is David Anstaett on behalf of defendants. We would be happy to take up the motion to strike first, because it certainly does have the possibility of limiting the scope of the preliminary injunction papers.

THE COURT: All right. Then in order to do that, do I need to hear from both sides in any further detail then as you briefed it about the scope of the case on remand, or is what you've laid out in your brief what you needed to tell me?

MR. BERL: Yes. I think that's true, Your Honor. There are a few sort of late-breaking issues, and we made reference to this in both our preliminary injunction papers as well as in yesterday's opposition to the motion to strike relating to a new patent that we expect to issue next month. I just want to make sure Your Honor is aware of that so that as Your Honor schedules further proceedings and considers the issues, Your Honor is aware of that so that there's no suggestion or understanding that we somehow were not up front about what was about to happen.

THE COURT: All right. Why don't you give me your perspective on that to make sure that I do understand what you've told me.

MR. BERL: Of course, Your Honor.

So we received from the patent office a notice of allowance of various claims. And per the usual procedure at the patent office, there is approximately five or six weeks between the notice of allowance and the issuance of a patent. The initial notice of allowance occurred, I believe, on March 3rd, and so we expect the patent to issue sometime in April. It happens on a Tuesday, so it could be April 12th, it could be April 19th, but sometime around that.

That patent that will issue next month addresses the exact same claim limitations that Your Honor already considered and that the Federal Circuit considered. That is the combination of all these ingredients like PVP K25 and PEG 1000 and HFA 227 and budesonide and formoterol in a single formulation. And it includes those limitations that Your Honor found to be a nonobvious set of ingredients and a nonobvious combination as affirmed by the Federal Circuit.

That patent does not include a limitation to 0.001 percent, which, as Your Honor knows, is the subject of Mylan's noninfringement defense. It broadens that range out to include from triple 05 percent to, I believe, .05 percent PVP, and xxxxxxxxx xxx xxxxxxxxxxxxxxx xxxxxxx xxxx xxxxx xxx xxxxxx xxx xxxx xx. xxxxxxxx'x xxxxxx xxxxxxxxx xx xxx xxxxxxxx xx xxx xxx xxxxxx, xxxxxxx xxx xxxxx xxxxxxx xxxxxxx xxxxxxxxx xxxx xxx xxxxxx and doesn't have a limitation to .001 percent as the

Federal Circuit construed that term with two significant digits.

In addition, that new patent does not require in the claim that the formulations be stable, and that limitation of stability is one that Mylan has fastened on in connection with the '247 patent that is the subject of the remand proceedings, asserting that that limitation about stability creates various problems under Section 112 like indefiniteness and lack of written description and enablement. Obviously, we disagree that there are problems, but any such problems or any such arguments are removed by virtue of the new patent issuance.

So in our view, Your Honor, this new patent sort of resolves the remaining issues. We don't think Mylan really has any tenable defense to this new patent to advance, and therefore, in our view, the issue here is essentially what happens between now and the issuance of this new patent on either April 12th or April 19th or some date around that.

Will Mylan be able to threaten to launch its product before then in those intervening weeks, or will the status quo be maintained until that new patent issues and the parties can resolve their disputes either at a preliminary injunction motion or we think preferably at a trial to be scheduled as soon as possible to resolve the remaining disputes on remand. So that's sort of how we see the issues and how we see the issuance of the new patent playing into those issues on remand.

THE COURT: All right. Thank you. Mylan's position on that scope of remand.

MR. ANSTAETT: Thank you, Your Honor. This is David Anstaett on behalf of defendants.

As the Court may have predicted, I disagree with, I think, literally everything that just came out of my friend on the other side's mouth.

He is referring to a patent that has not yet issued. How a patent that has not yet issued from the patent office can impact a pending temporary restraining order and PI proceeding is utterly and totally unclear. The short answer is it doesn't.

I heard a lot of attorney argument in the form of expert testimony about how there can be no invalidity challenge to this as-yet-to-be-issued patent, even though, as my friend on the other side admitted, it is a materially different patent than the ones that were tried previously, with a materially different PVP concentration and a different prosecution history.

AstraZeneca's problem is that this is a different patent. This patent -- it's not even a patent yet. It hasn't even issued from the patent office, and it won't, according to AstraZeneca, for at least another month.

The problem for them is how could they possibly, possibly get this into this case at this point. They can't.

They would have to move for leave to amend their complaint at this point. They would have to get the Court's permission to do that, and that would set off an entire discovery period on the scope of this patent, its prosecution history, the validity of the materially different PVP concentrations in this patent, and so to suggest that this is a simple matter of waiting a month for AstraZeneca then to assert this patent against us is, in our view, preposterous.

These -- patents don't just pop out of the patent office unanticipated. If AstraZeneca -- not if. AstraZeneca obviously had knowledge that they were prosecuting this patent in the PTO, and the fact that they never disclosed that to this Court, that they intended to bring it into this case, I just -- I'm almost at a loss for words to describe that.

Another important thing to appreciate, Your Honor, about this patent is that it is -- has the same priority date as all the other patents, which means that even if it does issue next month, it will then expire in a matter of months. And so that AstraZeneca would suffer any irreparable harm as a result of a theoretical argument that we might infringe a valid patent that hasn't issued yet is again preposterous. We are talking about a patent that will have a life of literally a matter of months.

They'll have to bring a new case if they want to assert this. And in that case they will not get a three-month

stay, because it will be late listed in the Orange Book, if they even manage to get it listed in the Orange Book. So this has no bearing on these proceedings. It is conjectural. It is speculative, and we absolutely oppose the notion that this is going to come into this case or PI proceedings or proceedings on the merit, and they haven't made any showing that it could.

And furthermore, if AstraZeneca views this new, yet-to-be-issued patent as an ironclad barrier to a potential Mylan launch of its product, then it doesn't need a preliminary injunction, and so I'll stop there to see if the Court has questions, but we absolutely oppose and disagree again with what my friend on the other side said.

THE COURT: Well, let me ask Mr. Berl a question.

Unless I missed it in your argument Mr. Berl, I didn't understand that you were asking me for permission to amend your complaint or to somehow inject this new patent that you expect to issue in April into the claims of this case, but are you?

MR. BERL: I am not, Your Honor. I did not say that. Correct.

THE COURT: Okay. What is the purpose of this argument?

MR. BERL: So I want to be totally up front here about what we expect to happen. In the event that Mylan is not either enjoined as of the time that that patent is issued, or

has agreed to stay off the market as of the time that that patent issues -- and again, the issue fee has been paid and it will be a matter of weeks before that patent issues -- then our present intention is to file a new complaint asserting that patent, and we would file a motion for preliminary injunction in connection with that patent immediately.

And so I don't want Your Honor to be surprised or misled when we have another preliminary injunction motion that we would file maybe even on April 12th, about three weeks from now, and so I think that's obviously relevant to how the parties proceed and how the scheduling will work.

I should say that Mr. Anstaett said at the end that we don't need a preliminary injunction because this patent is so ironclad, and it's worth noting that Mylan's own executives have repeatedly stated in the last couple weeks that they don't intend to launch until 2023. And the point is that we shouldn't have to take that risk of them threatening to launch, and that's why we think a preliminary injunction is warranted and necessary, notwithstanding the fact that we think it's very, very unlikely that, in the face of this new patent or even in the face of the existing patent, that Mylan would launch.

Mylan has never said it would launch. We've asked them. They haven't responded. Mylan has said that it's been approved by FDA, and we understand that to be the case, but we

do not have any reason to believe that Mylan, in fact, will launch.

And so the way we see this is that the parties and the Court are expending enormous resources to adjudicate a theoretical academic question of whether Mylan could launch, even though Mylan hasn't said that it will launch, and the Court may have to entertain one or even two preliminary injunction proceedings followed by a trial on duplicative issues.

And we think there's sort of a simpler and easier course here, and that is to try to get this case to trial as quickly as possible and have Mylan preserve the status quo until the Court can actually address these issues on a full record within a few months. That's how we think the case should proceed. We think that's most efficient and so that's our view.

THE COURT: Excuse me just a minute, Mr. Anstaett.

Mr. Berl, that was just a little vague for me in terms of understanding how you perceive this schedule to be from your theory-of-the-case perspective. Tell me again when you think this case should try and what should be included in it?

MR. BERL: So, Your Honor, at the first teleconference we had, I think back in January, early January, Your Honor had indicated that there may be some availability in

Your Honor's schedule during the first week of June. I don't know whether that remains the case or not. If it does, we think that the case would be prepared to be tried during the first week of June, and that schedule would accommodate any further discovery necessary with respect to Dr. Berkland's report and we could move forward and try the issues as they relate to the '137 patent as well as the '247 patent.

We don't think there are any different issues that are of any real significance with respect to the new patent. We think that the new patent could be tried at the same time. There are already reports that address virtually every limitation in those claims.

If there needs to be some short supplemental report on the issue, we think that can be accommodated over the next couple months, and rather than engaging in duplicative emergency proceedings, the parties can prepare this case to try it to Your Honor in the beginning of June.

THE COURT: That's what I thought you said. All right.

Now I'll hear from you, Mr. Anstaett.

MR. ANSTAETT: I have a number of points to make in response to that. As far as statements from Mylan management, Mr. Berl and AstraZeneca simply selectively quote those. This is from February -- this is from February 28th of 2022, an investor call, so while we have not included Symbicort court in

our 2022 financial guidance, we are happy with the progress on the product and will remain ready to launch if the opportunity presents itself in 2022. So that notion that Mr. Berl just told you about is false.

Sure, for AstraZeneca I imagine they do think it would be simpler and easier to simply keep us off the market until this Court holds a trial in June, and then whatever period of time expires after June when the Court will obviously need time to issue an opinion, what that is another way of saying is simply enjoin Mylan and keep them off the market because it would be simpler and easier for us.

That's not something they can just ask for. That is an extraordinary remedy that they have the burden of showing. And, of course, we've laid out those burdens and the arguments on that in our preliminary injunction papers.

The new patent can be addressed in the June trial, again, that is preposterous. This is a patent that hasn't even issued yet. First of all, AstraZeneca apparently wants us to address the tardy infringement report, literal infringement report, of Dr. Berkland that it never submitted on time, and we'll talk about that hopefully with respect to the motion to strike.

So we're going to do new expert reports on that literal infringement theory, expert depositions, more fact discovery. The Court will have to do claim construction with

respect to that, there will be a *Daubert* motion, and now we add an entirely new patent to the case according to AstraZeneca, at some point in April, when they file a new lawsuit. So they'll file a new lawsuit in April and take it to trial in June. I've never heard of such a thing.

The notion that all the previous discovery can just be used with this new patent is false. It can't be. There are new claims. If the claims were identical to the previously issued patents, they would have been rejected for double patenting and they would not issue. Of course there are different claims. And so this notion that this is all going to happen first in the context of their pending preliminary injunction motion and then before a trial in June we think is preposterous.

As to the notion that there will have to be two injunction proceedings, AstraZeneca has a massive irreparable harm problem, Your Honor. As we explained in our brief, they have already genericized the Symbicort market by launching their own authorized generic. They have done that already. Their patents are set to expire in a matter of months. The case law is virtually uniform that when you have a potential damages period over an incredibly short amount of time, the harm is not irreparable.

So if this Court were to determine, for example, in the current injunction proceeding, that AstraZeneca will not

suffer irreparable harm if Mylan launches at some point between now and when those patents expire, then there is no second injunction proceeding, whether they get a new patent or not.

So again, the ask here that they are making is incredible, and the prejudice that it would inflict on defendants who have spent years and xxxx xx xxxxxxxx xx xxxxxxx developing their generic products, which are finally approved by the FDA, would be extraordinary. And AstraZeneca cannot show that it's entitled to that kind of extraordinary relief.

MR. BERL: Your Honor, if I could respond --

THE COURT: You may respond briefly. Go ahead.

MR. BERL: Very briefly, Your Honor.

I still didn't hear from Mr. Anstaett that Mylan intends to launch its product. And so it remains the case that Mylan is asking the parties and Court to undertake an academic exercise so it can try to threaten AstraZeneca with launching a product that it doesn't intend to launch.

And I'll save the argument on irreparable harm for the day that we argue, if at all, the issue of the preliminary injunction, but suffice it to say that I completely disagree. The patent does not expire in a matter of months. It expires in the middle of 2023, in July of 2023. And more fundamentally, we showed irreparable harm and will show irreparable harm.

What we are trying to do is get to a point of

certainty, which is what the parties should want, and the fastest way to get certainty is to have a trial. If Mylan wins, they're allowed to launch the product. If not, they're not allowed to launch the product. Preliminary injunction proceedings won't create any certainty, because either way there'll still be a trial looming at which the final decision will be rendered.

And as for his point that it would be prejudicial to Mylan somehow to wait for adjudication on a full record until June, which I think is only a few months away, to address that possible prejudice we would be willing to post a bond to compensate Mylan for any time that it was improperly left off the market that it would have commercialized its product as a result of any decision that would set the trial and make this happen. And so that would redress, I think, any of the potential harm and prejudice that Mr. Anstaett referenced.

THE COURT: You know, briefly, but I'm aware that we've launched ourselves off into a world of preliminary injunction factors that really isn't relevant to me today in the lineup of issues that I have to decide. It may become relevant at some point, but I don't think right now it is, but you can briefly respond to that, Mr. Anstaett, with that understanding.

MR. ANSTAETT: Thank you, Your Honor. I will just briefly respond.

This notion that I didn't say that we will launch, I think, as we have explained to Your Honor, there is a competitive harm there. Of course AstraZeneca wants to know when we will launch, because they have an authorized generic on the market and they can take actions to restructure the market if they know precisely when we will launch, and that's why we have had in camera communications with the Court about that.

And so the notion that we are somehow obligated to tell Mr. Berl when that's going to happen is flatly false. The bond doesn't solve the problem for precisely that reason, because of the actions that AstraZeneca can take in the market while we would be held off the market and enjoined to restructure it and lock up long-term contracts and exercise its authorized generic in the market.

And finally, the last thing I'll say is this notion that, again, we should just wait until June, that's granting a de facto PI to AstraZeneca without them having to meet the formidable burden that they have to obtain that kind of relief.

So with that, I will not say anything further, Your Honor.

THE COURT: All right. Thank you.

And Mr. Berl, one fact question. Was Mr. Anstaett correct in telling me that the priority date for this new patent that you expect to launch next -- or not to launch, but you expect to issue next month is the same as the patents in

prosecution?

MR. BERL: It is the same. It is the same. It would expire in July of 2023, and it's an identical patent, same specification, exact same claims, other than it doesn't have 001 like the claims Your Honor tried. Instead, it has a broader PVP range that includes 001 and xxxxx'x xxxxxxxxxx.

THE COURT: Okay. All right. So now I think the question before me that we should turn to is whether AstraZeneca's xxxxxxxxxx theory in Dr. Berkland's supplemental report is within the scope of the case on remand, and that's a decision that I would like to make today. I've read your briefs, and if we can, we could just launch right into a discussion of these issues. Is there any objection?

MR. ANSTAETT: No objection from us, Your Honor.

MR. BERL: Nor from us, Your Honor.

THE COURT: All right. Now, obviously, I have a tremendous amount of discretion with regard to this, but I think what would inform my judgment and help me make the decision is how I should view this theory and when it was introduced in discovery, because from my review of the record, you know, this case came up -- was filed in Delaware and then ultimately your portion of it came to trial here, but my understanding is that the parties ultimately agreed to give the term its plain and ordinary meaning and that no construction of that term was necessary. And that occurred in Delaware,

correct?

MR. BERL: Yes, Your Honor.

THE COURT: All right. So after the case was transferred to this district, as I recall, Mylan filed a partial motion for summary judgment in which it relied on its proposed claim construction of 0.001 PVP with two significant digits, and AstraZeneca requested a status conference to discuss claim construction of 0.001 PVP.

Everybody with me so far? Are the facts the same for both sides?

MR. BERL: Yes, Your Honor.

MR. ANSTAETT: I think that's right, Your Honor. I think the parties jointly requested a hearing on that when the dispute arose, and then as Your Honor may come on to, that's when we first received -- after that is when we first received a new literal infringement report from Dr. Berkland.

THE COURT: All right. On July 13th of 2020, I held that status conference, and that's when AstraZeneca asserted to me that the defendants had waived their proposed claim construction when, in Delaware, they adopted the plain and ordinary meaning of 0.001 PVP in lieu of their two significant digit construction. At least that was AstraZeneca's argument.

It also argued that it hadn't produced an expert report on literal infringement under that proposed claim construction because it had understood the defendants to have

waived this construction.

Mylan contended that AstraZeneca was feigning ignorance of the proposed -- Mylan's proposed claim construction.

At that hearing I ultimately rejected AstraZeneca's argument that the defendants had waived their proposed claim construction and I ordered the parties to submit claim construction briefs. Everybody in agreement?

MR. ANSTAETT: Yes, Your Honor.

MR. BERL: Yes, Your Honor.

THE COURT: All right. So then between July 20th and July 27th, the parties exchanged emails in which AstraZeneca informed Mylan that it wished to submit an expert report containing an additional literal infringement theory, the so-called xxxxxxxxxxx theory that's under review today, right? Everybody agree?

MR. BERL: Yes, Your Honor.

THE COURT: Okay. Mylan rejected that proposal as untimely, and AstraZeneca then provided Mylan with a copy of the proposed supplemental report of Dr. Berkland, and Mylan sought an emergency status conference with me regarding the admissibility of that supplemental report.

And at that time that I held the hearing on August 4th of 2020, that report had never been filed. The defendants asserted that supplemental report was untimely and actually not

a true supplement because it was expounding a whole new opinion. And AstraZeneca countered that the defendants had waived their proposed construction and -- at least AstraZeneca has been led to believe that they had waived it and that it had not had an opportunity to develop this new theory during discovery because of that misapprehension.

And then, because I adopted AstraZeneca's proposed claim construction, the parties stipulated to infringement and the issue of the supplemental Berkland report and underdosing theory became a moot point. Does everyone agree?

MR. BERL: Yes, Your Honor.

MR. ANSTAETT: Yes, Your Honor.

THE COURT: All right. So then the question is whether I should allow the parties to reopen discovery on remand to take up this new expert opinion. And the questions before me are how is this going to prejudice either side, and is it going to delay a resolution of the case, and how probative is the evidence in the face of what could be described as a lack of diligence, and is there any prejudice -- if there's prejudice to both sides, which side has the better argument with regard to how unfair that prejudice is.

So what the Federal Circuit said, I think, is very important, and I'm quoting: In accordance with the judgment of this Court entered December 8th, 2021, and pursuant to Rule 41 of the Federal Rules of Appellate Procedure, the formal mandate

is hereby issued, but the opinion stated, quote, "We construe 0.001 percent as that precise number, with only minor variations, that is, 0.00095 percent to 0.00104 percent. We therefore vacate the stipulated judgment of infringement and remand for the district court to find in the first instance whether Mylan's ANDA product infringes the asserted claims under the proper claim construction."

And so what we're looking to, therefore --

MR. BERL: Your Honor --

THE COURT: Go ahead. I'm --

MR. BERL: I'm very sorry, Your Honor. This is David Berl. I really apologize. We somehow got disconnected from the call. I don't know how that happened. But I missed, unfortunately, the last probably 90 seconds of what was done or said.

THE COURT: Well, I was -- if you will just look at the mandate from the Federal Circuit, I was quoting that.

MR. BERL: Okay.

THE COURT: So what I'm saying now is in light of that mandate, infringement, in my view, is the subject of the remand, but whether AstraZeneca's xxxxxxxxxx theory should come into the case and discovery be reopened is within my discretion in light of that mandate.

And I take it as telling that AstraZeneca -- at the time that the parties stipulated to infringement, AstraZeneca

hadn't moved to file Berkland's supplemental report out of time. It was clearly out of time, as I believe I've stated before, and I don't believe AstraZeneca is disputing that it never filed the report.

Is that correct, Mr. Berl?

MR. BERL: That's correct, Your Honor.

THE COURT: Okay. So we now, I think, have to look -- just to move right through Rule 37 and then we're into the Southern -- what I call the *Southern States* factors. Do you all agree that that's where this case goes for analysis?

MR. BERL: Yes, Your Honor.

MR. ANSTAETT: Yes, I think we can look at the *Southern States* factors, Your Honor.

THE COURT: All right. So we start then with what I did in the scheduling order. And that scheduling order which, as you know, was entered after long discussion with the parties and taking into consideration all the dates that you had preferred and suggested when agreement couldn't be reached and I had to make the decision, the expert reports were due no later than January 15th, 2020, and the expert discovery was to close on August 10th, 2020.

So we go to July 18th, which is when AstraZeneca first notified Mylan of its intent to serve what it called a supplemental expert report. And in my view, I agree with AstraZeneca's argument that a supplemental expert report really

understates what the attempt is in that report, which had not been previously disclosed, and it's not -- it's a whole new opinion on xxxxxxxxxxx that had not been introduced into the case previously.

So if we look at the first factor, surprise to the defendants, I think that factor weighs in favor of excluding the report.

The second factor is the defendants' ability to cure surprise and disruption of the trial, which, in my view, based on the arguments I've read, are intertwined arguments. AstraZeneca argues it should be allowed to add its xxxxxxxxxxx theory, which tellingly it concedes would require reopening fact and expert discovery, and the argument is, well, we can do this very quickly, Judge. You don't have to worry about that, even though we all recognize that that would be very significant discovery. It's a whole new opinion and we now know that it will likely become intertwined with a patent that is -- I'm told is likely to issue next month or to -- yeah, to issue next month.

Mylan asserts that, in its view, in light of this opinion, additional claim construction would be necessary. Now, I haven't scheduled a trial date yet. That was to be done today, but there's no one on this call who understands that that trial -- it would be any later than June. And it's now March, the end of March. So to argue to me that reopening fact

and expert discovery and to do claim construction and to have a trial on the issues that were remanded as well as this new theory could all be done in March or April or even June is, I believe -- I don't want to say it's misleading, but it probably is, but at best, it's very Pollyanic. I'll leave it there.

And I know the case needs to be tried. There are compelling reasons why the case needs to be tried, whether it's got the xxxxxxxxxxx theory in it or it doesn't. And so while I see that there's prejudice to both sides if the theory is included or it isn't included, in my opinion, even though the prejudice to the defendants arguably could be cured through the reopening of fact and expert discovery and they therefore would not have the surprise that they had in July and early August of 2020, I find that they would be greatly prejudiced by the delay caused by developing the xxxxxxxxxxx theory because of the fact that they -- I think it's become plain on the record today that they have received FDA approval, and will be in a position, once these issues are determined, to launch or to determine whether they shouldn't launch their ANDA product.

I know AstraZeneca's moved for a temporary restraining order, a preliminary injunction to prevent the launch. But the proceedings to resolve that motion will have an impact on the trial schedule, and to attempt to develop an additional infringement theory simultaneously with that, in my view, would unfairly prejudice not only the defendants but

would significantly impact this Court's resources and ability to retry the case, as I've led you to understand, in either April or June of this year.

So in light of all of that, and all the deadlines that are necessary in this case, I find that those two factors weigh in favor of exclusion.

Now, turning to the importance of the evidence, in my opinion this factor weighs against exclusion, because undoubtedly expert opinions on infringement are crucial to AstraZeneca's case. And evidence related to its xxxxxxxxxx theory are important literally, but particularly with the Federal Circuit's instructions to the Court to adopt the defendants' construction of the term 0.001 percent PVF.

The fourth factor is AstraZeneca's explanation for its failure to disclose the underdosing theory. And I think this is a particularly important factor, because AstraZeneca argues that the reason it didn't introduce its underdosing theory earlier is because the defendants had misled it into believing they had forfeited the claim construction, that they had previously offered of 0.001 percent.

I find that this argument rings hollow. The defendants put AstraZeneca on notice of what they believed would be -- should be the proper construction of 0.001 percent in their paragraph four notice. While the parties agree to adopt the plain and ordinary meaning of that term, they never

defined that meaning with more specificity. So I find that AstraZeneca was not misled into believing that the defendants no longer believed 0.001 percent should be read to include two significant digits.

I also find that AstraZeneca's -- that Mylan's expert report alluded to this claim construction, but Dr. Berkland's reply report did not include opinions related to literal infringement under the defendants' construction. So add to that that in July I rejected AstraZeneca's argument that the defendants waived their proposed claim construction. Renewing it today does not make it any more persuasive to me, or I should say renewing that argument today doesn't make it any more persuasive to me.

The claim to have misunderstood the defendants' position on their proposed claim construction is -- I don't think is justified and does not -- certainly does not permit base disclosure of the new infringement theory. So that factor, in my view, weighs in favor of excluding the new opinion.

So while the xxxxxxxxxxx theory may be relevant, the fact that AstraZeneca never properly presented this theory while the case was pending before trial in a way that would permit the parties to develop it pursuant to the schedule in the case is telling, and permitting it to now develop it would open the door to issues beyond the scope of the mandate, in

violation of the mandate's letter and spirit, in my opinion.

The *Southern States* factors, therefore, weigh in favor of excluding this theory from the case, and I decline the invitation to reopen discovery to develop the theory introduced out of time that was never filed as part of the case before the parties entered their infringement stipulation.

That's my ruling on that, which I think obviously AstraZeneca objects to and that's noted for the record, but granting the motion to strike AstraZeneca's xxxxxxxxxx theory, which is docket number 508, I think leads us now to schedule the trial date as soon as we possibly can.

And in anticipation of a ruling either way, I assumed that you all have looked at your calendars and are ready to discuss with me the dates that I do have available. Okay?

MR. ANSTAETT: Yes, Your Honor.

THE COURT: All right. Now, we're looking whether I have anything left in April, and we had talked at one point about the fact that we might not be able to try this case in a linear series of days but might have to jump around a bit.

I have the dates of April 18th through 22nd available right now. And those will be the best dates. That's five trial days. I'd like to hear your availability.

MR. BERL: Yes, Your Honor. This is David Berl. We will make ourselves available for that. To be honest, I think especially given Your Honor's ruling, it's very unlikely that

five days of trial would be necessary. I think substantially less than that would be necessary. And so it may make sense to try to do it in the second half of that week.

Obviously, I haven't confirmed these dates with the experts, and we will have to make sure they're available, but we will do our best to make sure that happens.

THE COURT: All right. Well, as you know, I will -- maybe you don't, but I have indicated that in these patent cases, because of the difficulty in procuring your witnesses' physical presence here in Clarksburg, I'm more than willing to continue to conduct the trial, in whole or in part, on Zoom so that at least with regard to your expert witnesses you can have those people from wherever they are for the period of time you need them. And I'm more than willing to continue to do that also, if you just want to try the whole case that way.

The problem I have with Friday the 22nd is not something I can't reschedule. I've got issues on Friday the 22nd, but I can reschedule, so if you don't want to start on Monday the 18th and would prefer Tuesday or Wednesday start, I can do that for you. But I don't want to make it less than three days, Mr. Berl, unless you and Mr. Anstaett and your whole team get together and let me know that.

I'm more than happy to hear back from you all if this date works for both sides and you want to massage which days of the week to use.

MR. BERL: That's very appreciated, Your Honor.

THE COURT: Sure. I will tell you starting the 25th of April I've got -- I'm in trial for the next two weeks, so -- no. Actually, I'm out of town the week of the 25th and then in trial for the next two weeks, so these dates are -- they're important to put down on the calendar.

And to use these dates we're going to have to be down -- if we're live, we're going to have to be in the bankruptcy courtroom. If we're on Zoom, we can do it -- I can be there, but you don't have to worry about that. But I don't have the courtroom in the main courthouse available to me that -- during any of that period of time again until June.

MR. ANSTAETT: Your Honor, we -- I do have to inform the Court that in anticipation of this we have been checking availability of our experts, and when we last checked, which was fairly recently, our main expert on invalidity of the '247 patent is unavailable from April 16th to 24. We can recheck that, but I am somewhat concerned that that will be an issue. And as I say, I'm happy to recheck that, but I do want to be very up front with the Court about that.

THE COURT: Well, that's going to be your problem, Mr. Anstaett, because we don't -- I don't have anything else available until June, and if you all want a decision from me before I retire on September 30th, the sooner we try this case the better. And if you all can work out to take him de bene

esse prior to trial and just submit his testimony that way, I'm fine with that.

MR. ANSTAETT: We will explore that, Your Honor. Thank you very much for that.

MR. BERL: Your Honor, this is David Berl again. Obviously that schedule is very appreciated and we appreciate Your Honor making time to try this case so expeditiously. As Your Honor knows, I have another trial between now and then, and that's obviously my problem and I'll deal with that, but do I understand Your Honor to be preserving the status quo, or the status quo will be preserved pending that trial so that we don't need to spend the intervening few weeks briefing and presenting preliminary injunction issues and instead we can just proceed straight to trial with the status quo maintained?

THE COURT: Well, sounds like you're looking for an advisory opinion from me on what I'd do on a PI. I think that's up to you two to decide, or your two sides to decide and let me know. If I have to jump in on a PI, I'm just going to have to jump in on it, but I can't just tell you you're ordered to preserve the status quo without going through what the analysis must be.

MR. ANSTAETT: Thank you, Your Honor. We certainly agree with that from our perspective.

THE COURT: Okay.

MR. ANSTAETT: Should make clear for the record we

agree with the analysis that you just stated, Your Honor, not with what Mr. Berl said.

THE COURT: What I would tell you all is that I'm in trial the week of the 5th. I have -- if you're anticipating that we're going to need a PI -- and by the way, the way I read the submission, you're not -- you were not looking for TRO, because that would have been very time sensitive, and I did consider this in the light of a preliminary injunction and that's really the way you're considering it, correct?

MR. BERL: Yes, Your Honor. Well, I'm not sure if I can say this on the line.

THE COURT: Nothing's launched yet, so this is all anticipatory.

MR. BERL: Correct. And it's our understanding that we'll have some notice so that we won't wake up one morning with our market wrecked without having an opportunity to come before Your Honor and present our PI.

THE COURT: I don't have that crystal ball, so if you're looking for that assurance from your opposing counsel, you all better have that conversation. In light of the developments in this case over the last couple of months, I don't believe that it's appropriate for me to be part of those discussions.

You all can let me know what your -- what factors your clients consider and how they will resolve that or not,

but otherwise I will simply tell you that during the week running up to the Easter holiday, although I have other matters, particularly one on the 13th involving Mylan in another case, I could do a remote hearing with you that week if -- and you'd have to let me know on a PI and you'd have to let me know how many witnesses you would have and how long it would take, okay? But I think that would have to be by Zoom, if it's necessary.

MR. ANSTAETT: Understood, Your Honor. And certainly we think that's fine and we would not even necessarily need witnesses in a PI hearing, if they want to have a hearing on it. It might be helpful -- as Mr. Berl said earlier, we have filed our response papers on the PI before they were due in order to kind of be prepared in the event we need to be.

I wonder if -- it might help if Mr. Berl could let us know if AstraZeneca intends to file any reply submissions, and if so, if we could set a -- an expedient deadline if there are going to be any of those, just so we would be in a position, everything would be ripe.

MR. BERL: I think it won't surprise Your Honor to hear that AstraZeneca does intend to submit reply papers.

THE COURT: I'm sure you do.

Let me just, for your information, tell you that I am not available in the next two weeks. I have another trial and there's nothing that is going to allow me, with a jury sitting,

to get into a midday hearing or status telephone call or something like that, so the rest of this week is when I need to hear back from you all about the schedule, both with regard to the trial and taking witnesses out of time, and also your -- where you would like me to block out time for a PI, if necessary. And I think that time in April that I've suggested I did have time works in a way, because it also relates to when the new patent might issue.

So taking all of that into consideration, obviously if there is going to be an issue for PI, then I need to know sooner rather than later because of this trial schedule I have.

MR. BERL: Absolutely, Your Honor. We will engage in discussions with Mr. Anstaett and Ms. Bloodworth and report back.

THE COURT: All right. So then tentatively we've got the week of April 18th through 22nd, likely not five days, but you'll let me know, and likely Mylan is going to need to take the testimony of -- its trial testimony of its main expert out of time and use it during trial in a de bene esse fashion; is that correct?

MR. ANSTAETT: Your Honor, yes, we will certainly explore that option. And as I said, we will check schedules again, but we will explore that option if there is still an availability problem for sure.

THE COURT: All right. Well, the only other option I

can offer you is sometime at the beginning of June. I don't have a number of dates available, but I do have June 1 through 3, June 6 through 10, June 13 through 17.

MR. ANSTAETT: And I know that our expert is available in that early June window, the first June window -- the earliest that you mentioned, so we will take that under consideration as well.

THE COURT: All right. I think it goes without saying that I have -- maybe I should say it, I think I did say it in another hearing. I have another patent trial starting May 23rd, and my decisions in these cases, you know, are basically based on who got tried and when. And if you don't go in April, you're likely to be decided after that case. I can't do a Solomon-like split of my body and decide you all while I'm deciding that, so take that into consideration.

MR. ANSTAETT: Understood, Your Honor.

THE COURT: Anything else we need to discuss today?

MR. BERL: No, not from AstraZeneca, Your Honor. Thank you for your time.

THE COURT: You're welcome.

MR. ANSTAETT: Not from Mylan, Your Honor, other than for me to correct our statement that our expert is available the week of June 5th, but as I said, we will check those earlier dates and talk to Mr. Berl and get back to the Court expeditiously. And again, we thank the Court for its time

today.

THE COURT: All right. And once I know where -- what the schedule is going to look like based on your discussions, my law clerk will probably be in conversation with your -- both sides' local counsel just to figure out deadlines without the need to get into a last-minute scheduling conference or final pretrial. I don't think we need to pretry this, based on the status of the case. We know what's coming, right?

MR. ANSTAETT: I think that's right, Your Honor.

MR. BERL: I'm not sure that's right, Your Honor. I think it depends on what Mylan intends to do and when with respect to its defenses, but I think if it's possible, Your Honor, if we can't reach agreement on things, that we can maybe reach out to Your Honor and hope to at least present the issues in writing before trial, if there are any pretrial issues that would remain outstanding.

THE COURT: All right. We'll see. I'll wait to hear what develops, but thank you all very much. Have a nice afternoon.

(Proceedings concluded at 2:07 p.m.)

CERTIFICATE

I, Cindy L. Knecht, Registered Professional Reporter and Official Reporter of the United States District Court for the Northern District of West Virginia, do hereby certify that the foregoing is a true and correct transcript of the proceedings had in the above-styled action on March 22, 2022, as reported by me in stenotypy.

I certify that the transcript fees and format comply with those prescribed by the Court and the Judicial Conference of the United States.

Given under my hand this 28th day of March 2022.

/s/Cindy L. Knecht

_____

Cindy L. Knecht, RMR/CRR
Official reporter, United States
District Court for the Northern
District of West Virginia